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Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

UNITED STATES OF AMERICA,)

Plaintiff,)

v.)

TOBY MCADAM,)

An Individual,)

d/b/a RISINGSUN HERBAL)

HEALTH CORP.,)

d/b/a RISINGSUN HEALTH,)

d/b/a RISINGSUN)

NUTRITIONAL CORP.,)

d/b/a RISINGSUN)

MINISTRIES,)

d/b/a NUTRITIONAL)

SUPPLEMENTS INC.,)

d/b/a MCADAM HEALTH)

ENTERPRISES CORP.,)

Defendant.)

Civil No. CV-10-128-SPW

**UNITED STATES' REPLY TO
DEFENDANT'S RESPONSE TO
PETITION AND BRIEF TO
SHOW CAUSE WHY TOBY
MCADAM SHOULD NOT BE
HELD IN CRIMINAL
CONTEMPT, RESPONSE TO
MCADAM'S MOTION TO SHOW
CAUSE WHY FDA SHOULD NOT
BE HELD IN CIVIL CONTEMPT
AND RESPONSE TO MCADAM'S
MOTION TO DISMISS**

NOW INTO COURT, through undersigned counsel, comes the United States, who files this reply to Defendant Toby McAdam’s (“McAdam”) response to the government’s petition and brief for and order to show cause why McAdam should not be held in criminal contempt (“Criminal Contempt Petition”). In addition, the United States files responses to McAdam’s motion to show cause why the United States Food and Drug Administration (“FDA”) should not be held in civil contempt and motion to dismiss.

I. INTRODUCTION

On July 29, 2015, the United States filed a Criminal Contempt Petition against McAdam for contumacious conduct related to this Court’s Consent Decree of Permanent Injunction (“Consent Decree”) entered on November 5, 2010, and Order of civil contempt entered on December 4, 2013. *See United States v. McAdam*, CV 10-128-SPW (D. Mont. 2010) (Docs. 5; 49; 78). On August 4, 2015, McAdam filed his response to that petition as well as a motion to show cause why FDA should not be held in civil contempt and a motion to dismiss the civil action *in Toto*. (*Id.* Doc. 80).

II. ARGUMENT

A. **McAdam's Response Fails to Provide Any Justification for His Failure to Comply with the Consent Decree and Order of Civil Contempt**

In an attempt to dissuade this Court from issuing an order to show cause, McAdam argues that the government's petition is moot because the case has been stayed by the United States Supreme Court. To support his position, McAdam referenced a letter dated July 21, 2015, from Scott S. Harris, the Clerk of the United States Supreme Court. (*See id.* Doc. 80-1). That letter indicates that McAdam's petition, which concerns the Ninth Circuit Court of Appeals' affirmation of this Court's December 4, 2013 Order of civil contempt, was returned to McAdam due to filing deficiencies and provides McAdam 60 days to correctly refile his petition. *Id.* Of note, the letter does *not* mention anything regarding a stay of any proceedings related to McAdam, the case at hand or the Criminal Contempt Petition filed against McAdam. *Id.* In fact, although McAdam previously requested stays from both this Court and the Ninth Circuit related to the Order of civil contempt, each request was denied. *See United States v. McAdam*, CV 10-128-SPW (Docs. 56; 76). As a stay has not been issued in this case for any reason, McAdam's argument should be rejected by the Court.

McAdam also argues that the Criminal Contempt Petition should be dismissed because he claims:

1. Lugol's iodine is not a dietary supplement;
2. Lugol's iodine is not a drug;
3. McAdam is not prohibited from selling products that are not specifically referenced in the Consent Decree; and,
4. The U.S. Drug Enforcement Agency regulates iodine.

To support his position regarding iodine not being a dietary supplement or drug, McAdam referenced what appears to be a product sales listing for Lugol's iodine from a completely unrelated chemical manufacturing company called Northwest Scientific, Inc. (*See id.* Doc. 80-3). McAdam claims that as Lugol's iodine is sold by chemical manufacturing companies, it cannot be a drug or dietary supplement. McAdam is wrong.

The Lugol's iodine McAdam sells is a dietary supplement as defined by the Federal Food, Drug, and Cosmetic Act ("FDCA") because it is a product, other than tobacco, intended to supplement the diet that contains a mineral and is intended to be ingested as a liquid. *See* 21 U.S.C. § 321(ff). As identified in the Criminal Contempt Petition, McAdam sold a bottle of Risingsun Nutritional Lugol's iodine to an undercover FDA agent in January 2014. *See United States v. McAdam*, CV 10-128-SPW (Doc. 78 at ¶19-20). The label on that bottle of Lugol's iodine, attached hereto as Exhibit 1, indicates that the iodine "Supports Thyroid Health" (*i.e.* it intends to supplement the diet), it is made from iodine (*i.e.*

a mineral) and it can be taken internally (*i.e.* it is intended to be ingested as a liquid). Thus, McAdam's own labeling renders his Lugol's iodine a dietary supplement.

In addition, and as identified in the Criminal Contempt Petition, McAdam sold a bottle of Nutritional Supplements, Inc. Lugol's iodine to an undercover FDA agent in April 2015. *See United States v. McAdam*, CV 10-128-SPW (Doc. 78 at ¶¶23-24). For the same reasons as listed above that bottle of Lugol's iodine is a dietary supplement. *See* Ex. 2. However, in August 2014, McAdam claimed on the Risingsun Health Facebook that his Lugol's iodine was intended to cure and treat diseases. *See* Ex. 3. More particularly, McAdam wrote:

People have been worried about ebol[a].... I have Lugol's iodine and over 200lbs of potassium iodide available when needed. Iodine is one of the best water purifiers and disinfectants, one other fact; it kills parasites, bacteria, fungus's [*sic*] and viruses. Ebol[a] is a virus Lugol[']s kill the virus, to[o] bad it hasn't been tested. That's right, it has been tested with positive results, so why isn't being used. I will keep you updated regarding the present health danger the world is facing. [L]ugol's iodine is as essential as having asp[i]rin on hand.

Id. at 3. McAdam's claim that Lugol's iodine is intended to cure or treat Ebola renders McAdam's Lugol's iodine a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B). It is also a new drug, subject to the FDCA's premarket approval requirements, because it is not generally recognized by experts as safe and effective for such intended uses. 21 U.S.C. § 321(p). Before McAdam could lawfully market and sell Lugol's iodine to consumers as a cure or treatment for

Ebola, FDA would have had to review and approve an application demonstrating that the product is safe and effective for its intended uses. 21 U.S.C. § 355(a).

McAdam's Lugol's iodine is not the subject of any application approved by FDA (e.g., New Drug Application ("NDA"), Investigative New Drug Application, or Abbreviated New Drug Application), or otherwise exempt from the FDCA's new drug approval provisions. Therefore, McAdam's Lugol's iodine is an unapproved new drug.

McAdam further argues that he is allowed to sell any product that is not specifically referenced in the Consent Decree. This is not true. The Court's Order of civil contempt requires McAdam "to immediately cease all manufacturing, processing, packaging, labeling, holding, selling, and/or distributing all products intended to be ingested by, or applied topically to, humans or animals, including, without limitation, any drugs and/or dietary supplements." *See United States v. McAdam*, CV 10-128-SPW (Doc. 49 at 2). As such, McAdam is barred from selling drugs and dietary supplements.

Finally, McAdam argues that the United States Drug Enforcement Agency ("DEA") regulates iodine and, because of that, FDA cannot regulate the sale of iodine. To support his argument, McAdam attempts to compare *FDA v. Brown and Williamson Tobacco Corp.*, 529 U.S. 120 (2000), to his situation. McAdam's argument is misplaced.

Iodine is a List 1 chemical, as defined in 21 C.F.R. § 1300.02(b)(3).

Because 5% iodine is a methamphetamine pre-cursor, DEA has an interest in and regularly inspects List 1 chemical manufacturers. However, DEA's interest in protecting the public from mass manufacture and distribution of 5% iodine as a methamphetamine pre-cursor in no way limits FDA's ability to regulate drugs and dietary supplements. Accordingly, McAdam's position is a *non sequitur* and should be disregarded.

B. McAdam's Petition for Civil Contempt Fails to Allege a Violation of the Consent Decree

McAdam argues that FDA is in violation of the Consent Decree for failure to approve dietary supplement labels that McAdam previously submitted to FDA. This argument is not new as evidenced in McAdam's Response to the Court's Findings and Recommendations which recommended that McAdam be held in civil contempt. *See United States v. McAdam*, CV 10-128-SPW (Doc. 48 at 2). The Court considered McAdam's filing and still held him in civil contempt. (*Id.* Doc. 49). McAdam now seeks to rehash arguments already ruled upon by the Court.

However, even if McAdam is not foreclosed from raising the issue, the Court can dismiss McAdam's argument outright. For McAdam to obtain approval of dietary supplement labels and then return to business, the Consent Decree requires that McAdam:

1. Notify FDA in writing of his intent to manufacture and distribute dietary supplements;
2. Hire an independent labeling expert who is qualified to review McAdam's product labeling and determine if the labels comply with the FDCA;
3. Notify FDA of the identity and qualifications of the labeling expert;
4. Have the labeling expert perform a comprehensive review of the dietary supplements McAdam wishes to sell; and,
5. Have the labeling expert submit a written report to FDA analyzing whether McAdam is in compliance with the FDCA.

See id. Doc. 5 at 8-10.

McAdam testified during the Civil Contempt hearing that he hired a labeling expert and he believed that expert forwarded labels to FDA. *See* Ex. 4 at 58-63 (transcript of selected testimony from Civil Contempt Hearing, Oct. 21, 2013).

However, FDA compliance officer Lisa Althar testified that, although she received labels directly from McAdam, she never received labels from his labeling expert and she never received a comprehensive review of the dietary supplements that McAdam wished to sell. *Id.* Accordingly, as McAdam has not complied with the methodology that he agreed upon using to obtain approval of dietary supplement labels as defined by paragraph 5 of the Consent Decree, FDA cannot be in civil contempt for failure to approve his labels or allow him to go back into business.

McAdam also claims that FDA violates his rights to equal protection by prohibiting him from selling drugs and dietary supplements. McAdam signed a Consent Decree that was entered by the Court on November 5, 2010, wherein

McAdam agreed to stop selling drugs and dietary supplements until FDA allowed him to resume operations. In addition, as noted above, the Order of civil contempt of December 4, 2013, bars McAdam from selling drugs and dietary supplements that can be consumed by man or animal. McAdam's equal protection claim is specious and his motion should be dismissed.

C. McAdam's Motion to Dismiss is Meritless

McAdam moves this Court to dismiss the civil case *in Toto* because of an alleged violation of Rule 4 of the Federal Rules of Civil Procedure. More particularly, McAdam complains that he was not served with either the complaint or a summons following the government's filing of its complaint against McAdam. *See generally* Fed. R. Civ. P. 4(c). The following brief pre- and post-filing case history is added for context.

On August 31, 2010, undersigned counsel sent correspondence to McAdam indicating that he was in violation of the FDCA and that a civil complaint would be filed to address those violations. *See* Ex. 5. In addition, the letter offered McAdam the ability to negotiate a consent decree and urged McAdam to consult with counsel regarding the proposed consent decree. *Id.* McAdam hired counsel, who then negotiated the consent decree on behalf of McAdam. McAdam and his counsel agreed and signed the negotiated Consent Decree. *See United States v. McAdam*, CV 10-128-SPW (Doc. 5). On October 13, 2010, undersigned counsel

filed via the Court's electronic filing system the Complaint, proposed Consent Decree, and Certificate of Counsel. (*See id.* Docs.1-3). The Certificate of Counsel attests that the Complaint and Consent Decree were served on McAdam's counsel on October 13, 2010. On that same day, undersigned counsel forwarded the filed documents via electronic mail and FEDEX to McAdam's counsel. *See* Exs. 6 and 7. On October 15, 2010, undersigned counsel filed an Unopposed Motion to Enter Consent Decree of Permanent Injunction advising that the parties were not opposed to the Court entering the filed Consent Decree. *See United States v. McAdam*, CV 10-128-SPW (Doc. 4). The government did not request or serve a summons on McAdam. However, McAdam's motion to dismiss is without merit.

McAdam's argument that he was not served with the government's complaint is false. As noted above and as identified in the record, the complaint was served upon McAdam through his counsel of record on October 13, 2010. There is no deficiency under Rule 4 of the Federal Rules of Civil Procedure.

Even though it is true that the government did serve McAdam with a summons, McAdam has waived any defense of lack of insufficient service of process. "Defects in personal jurisdiction, venue, or service of process are waived unless asserted in a party's initial pleading." *Hill v. Blind Indus. & Servs.of Maryland*, 179 F.3d 754, 757 (9th Cir. 1999) (citing Fed. R. Civ. P. 12(h)(1)). "A fundamental tenet of the Federal Rules of Civil Procedure is that certain defenses

under Fed. R. Civ. P. 12 must be raised at the first available opportunity or, if they are not, they are forever waived." *Boston Telecomms. Group, Inc. v. Deloitte Touche Tohmatsu*, 249 Fed. App'x. 534, 537 (9th Cir. 2007) (quoting *American Ass'n of Naturopathic Physicians v. Hayhurst*, 227 F.3d 1104, 1106 (9th Cir. 2000)).

McAdam's appearance, through the filing of the signed Consent Decree, constitutes a waiver of any later defense of lack of insufficient process.

Accordingly, McAdam's argument is nothing more than another attempt to be rid of the restrictions to which he agreed in the Consent Decree as well as additional restrictions placed upon him by the Court in the Order of civil contempt.

See United States v. McAdam, CV 10-128-SPW (D. Mont. 2010) (Docs. 8; 13); *see also McAdam v. FDA, et al.*, CV 12-137-BLG-RFC-CSO (D. Mont. 2012); *McAdam v. FDA, et al.*, CV 14-47-BLG-SPW-CSO (D. Mont. 2014). McAdam's motion should be dismissed.

III. CONCLUSION

McAdam's response to the government's petition and brief for an order to show cause why he should not be held in criminal contempt provides no justification for why the Court should dismiss that petition. McAdam cites no law nor legal precedent, and only makes specious claims that are, at best, misinformed and, at worst, misconstrue and hide the truth. We respectfully request the Court

issue an order to show cause why McAdam should not be held in criminal contempt.

McAdam's petition to hold FDA in civil contempt and his motion to dismiss the civil case *in Toto* attempts to misdirect the Court away from McAdam's contumacious conduct. The government requests the Court dismiss both motions.

Dated: August 18, 2015

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CERTIFICATE OF SERVICE

The undersigned hereby acknowledges that the foregoing Reply and Responses were served on Toby McAdam in the modes used in prior filings: via email and placing into FEDEX, on this 18th day of August, 2015.

/s/ David Sullivan
DAVID SULLIVAN

CERTIFICATE OF COMPLIANCE

The undersigned hereby acknowledges that the foregoing Reply and Responses contain 2,361 words, excluding the caption and certificate of service.

/s/ David Sullivan
DAVID SULLIVAN